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1 RECORD OF ORAL HEARING
2 UNITED STATES PATENT AND TRADEMARK OFFICE

3
4 BEFORE THE BOARD OF PATENT APPEALS
5 AND INTERFERENCES

6
7 *Ex parte* RONALD L. REAM, MICHAEL J. GREENBERG,
8 WILLIAM J. WOKAS and CHRISTINE L. CORRIVEAU

9 Appeal 2009-001864
10 Application 09/990,628
11 Technology Center 1600

12 Oral Hearing Held: June 25, 2009

13
14 Before DEMETRA J. MILLS, LORA M. GREEN, and
15 MELANIE L. McCOLLUM, *Administrative Patent Judges*.

16 APPEARANCES:

17
18 ON BEHALF OF THE APPELLANTS:

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24
25

PROCEEDINGS

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MS. BEAN: Calendar No. 69. Mrs. Lynch.

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JUDGE MILLS: Okay, great. Thanks.

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MS. LYNCH: Hi. I was going in the other room. I apologize.

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JUDGE MILLS: Oh. Do you have a business card for the court

6

reporter?

7

MS. LYNCH: I do. The spelling of the reference is on the back.

8

COURT REPORTER: Thank you.

9

JUDGE MILLS: Oh, good. Prepared.

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MS. LYNCH: I try to be.

11

JUDGE MILLS: Well, we are familiar with the facts in your case,

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and if you'd just like to focus on your most important points, that would be

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helpful to us. You have 20 minutes.

14

MS. LYNCH: Okay. Well, first of all, good morning.

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JUDGE MILLS: Good morning.

16

MS. LYNCH: My name is Rachel Lynch. I'm here on behalf of

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appellants for U.S. Serial No. 09/990,628. The issue on appeal includes just

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one obviousness rejection. As I will discuss, and as I hope you will agree,

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the rejections are improper as a matter of fact and law.

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If you are familiar with the claimed invention, I'll jump right into the

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rejections.

22

JUDGE MILLS: We are.

23

MS. LYNCH: Okay. The Examiner has rejected claims 9 through 26

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under 103 as being obvious in view of the combination of the 838 patent to

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Cherukuri and the 436 international publication to Stahl. Appellants

1 respectfully submit that the rejections are improper as a matter of fact and
2 law, because the cited references, either alone or together, fail to disclose
3 each and every element of the present claims, and alternatively, Stahl
4 teaches away from both Cherukuri and the present claims.

5 Now independent claims 9 and 18 recite, in part, products or chewing
6 gum having a chewing gum center and a coating including a medicament
7 wherein the coating comprises at least 50 percent by total weight of the
8 product. As I stated, Cherukuri and Stahl fail to disclose each and every
9 element of the present claims. For example, Cherukuri is directed toward a
10 one-step or one-syrup method for providing sugarless coatings on a solid
11 center which includes coating alternating layers of a syrup and a dusting
12 compound. Rather than teaching amounts of the coating with respect to the
13 entire product, Cherukuri is primarily concerned with the components of the
14 coating syrup and the dusting mix as well as specific ingredient percentages
15 within the coating syrup and the dusting mix, for example, meaning that
16 they're focused on having a polyol such as sorbitol and not xylitol, so
17 they're more focused on what exactly does the coating comprise.

18 In fact, the only times in the entire disclosure of Cherukuri that any
19 percentages of a coating with respect to the entire product are mentioned, the
20 highest and the only coating mentioned is 35 percent. Now in response, the
21 Examiner asserts that Cherukuri teaches a coating that can include
22 medicaments. The Examiner states this in the Examiner's Answer at page 3.

23 Now in contrast, Appellants submit that this is just misunderstanding
24 of the disclosure of Cherukuri. In fact, Cherukuri states at column 1, lines 9
25 through 14, and column 5, lines 55 through 60, that the entire purpose of

1 Cherukuri is to coat, for example, a pellet or a tablet with a coating where
2 the medicament is in fact the center component that gets coated. So
3 Cherukuri does not disclose anywhere in the entire disclosure that that
4 coating actually comprises a medicament.

5 Now the Examiner further asserts that Cherukuri teaches one of skill
6 in the art how to obtain at least 50 percent by weight coating since it teaches
7 that 12 -- 10 to 12 coats of coating syrup and seven to nine coats of dusting
8 mix are required for a coating that is 35 percent by weight of the chewing
9 gum. Now based on these numbers, the Examiner just concludes that
10 anyone skilled in the art by routine experimentation could calculate the
11 number of sugar coatings and dusting mixes that are required to achieve the
12 35 percent coating. Now Appellants respectfully disagree and submit that
13 there is no reason that the skilled artisan at the time of this invention would
14 have had any reason to change a coating level from 35 percent to the
15 presently claimed over-coated chewing gum level of at least 50 percent.

16 So for example, the specification clearly states that typical chewing
17 gums don't have a coating level anywhere near 50 percent. Instead, typical
18 chewing gums have a coating level that's much lower than 50 percent, and
19 this is bolstered by the argument that the Examiner couldn't even find one
20 piece of prior art that cites a chewing gum having a coating level anything
21 over 35 percent. This is, in fact, the best that the Examiner could do when
22 considering at the time of the invention what was going on in the prior art.
23 As a result, the Examiner is then forced to argue that it would have been
24 obvious that the skilled artisan would include such a coating level.

25

1 However, in order for the obviousness rejection to be proper, the
2 Examiner must establish a reason why the skilled artisan would want to
3 achieve such an over-coated level of 50 percent. By failing to cite any prior
4 art references that even get close to 50 percent, Appellants submit that the
5 Examiner has failed to provide any reason for achieving same. Moreover,
6 the fact that the Examiner could not find any prior art disclosing such
7 coating levels, as I discussed before, points to what the state of the art was at
8 the time of the invention and indeed bolsters the argument that it is in fact
9 novel to have such over-coated chewing gum coating levels.

10 So Appellants also submit that simply because Cherukuri teaches
11 varying the number of syrup and dusting mix levels, this doesn't make it
12 obvious to include a coating of at least 50 percent by weight. In fact, this
13 begs the question, absent a hindsight reconstruction, why would the skilled
14 artisan have wanted to achieve a coating level of at least 50 percent. In
15 contrast, using this logic by the Examiner, Cherukuri may teach, for
16 example, a 1 percent coating level with 99 percent chewing gum. But in this
17 case, it's just not going to work because that 1 percent coating isn't going to
18 provide enough medicament to achieve a medicinal purpose. Now in
19 contrast, using the same logic, if Cherukuri teaches 99 percent coating and 1
20 percent chewing gum, then this also isn't going to be a feasibly economical
21 product, because the 1 percent of chewing gum not isn't going to achieve the
22 intended purpose of the product which is chewing gum.

23 So Appellants submit that the Examiner's unjustified conclusion that
24 50 percent would have been obvious just isn't proper rationale for such a
25 rejection.

1 JUDGE GREEN: So is it your understanding that the Examiner is
2 basically saying that any level of coating would have been obvious to the
3 ordinary artisan?

4 MS. LYNCH: Well, the Examiner states that because Cherukuri says
5 that 10 to 12 levels of syrup and 7 to 9 levels of dusting mixture, using that
6 rationale and that you would use that to achieve a desired thickness --

7 JUDGE GREEN: But basically, I mean he is saying that you could
8 use the teachings of the Cherukuri reference to get up to 50 percent. Your
9 argument -- his argument appears to be you could do it for any desired level
10 of coating, so any desired level of coating would have been obvious, and it's
11 your position that it seems to me that without some reason to go up to those
12 high levels that the references don't provide that.

13 MS. LYNCH: Well, that's right, and, in fact, when you look at that
14 rationale it just doesn't hold up with any level to achieve any desired
15 thickness level, because as I stated, 1 percent chewing gum wouldn't have
16 the intended purpose of a chewing gum, and you know, 1 percent coating
17 isn't going to provide the medicinal purposes here. So yes, that is my
18 argument, that it's an unjustified conclusion that any desired thickness and
19 any coating level can be attained from Cherukuri. Instead, we would submit
20 that the Examiner needs to point to something that provides a rationale to
21 depart from typical chewing gum levels in order to optimize a chewing gum
22 having 50 percent coating which could deliver medicinal -- a medicinal in
23 the amount necessary here.

24

25

1 JUDGE MCCOLLUM: Let me just confirm something. In
2 Cherukuri, it's the inside that is the chewing gum, and it contains the
3 medicament inside, so the coating is basically there to coat it, basically.

4 MS. LYNCH: Yeah, exactly, and --

5 JUDGE MCCOLLUM: Or to make it hard.

6 MS. LYNCH: Yeah, and there are chewing gums on the market right
7 now where the coating doesn't provide any medicament or anything like
8 that. It's just a coating for sometimes they have encapsulated flavor
9 ingredients in there or something so that when the consumer bites into it it
10 releases a flavoring --

11 JUDGE MCCOLLUM: Right.

12 MS. LYNCH: -- quicker or something like that, where this invention
13 actually provides the medicament in the coating which Cherukuri doesn't do.
14 It specifically says that this can be your medicament, and this is your
15 coating.

16 JUDGE GREEN: But to be fair, Stahl, the PCT --

17 JUDGE GREEN: -- does teach that you can put it in the coating,
18 right?

19 MS. LYNCH: It does. It does teach --

20 MS. LYNCH: -- that you can put it in the coating. Neither of the
21 references, however, would provide the over-coated chewing gum that
22 Appellants are claiming now which would be over 50 percent which is well
23 above anything that was in the prior art at the time of this invention and well
24 above anything that you would find on the market currently.

25

1 JUDGE MILLS: You had indicated that there was a teaching away in
2 Stahl. Would you like to address that?

3 MS. LYNCH: Sure. Stahl teaches, for example, the typical chewing
4 gum process which is, as we stated in the specification, as is also discussed
5 in Stahl, sort of a three-step manufacturing process which includes, first of
6 all, like accrued coating, where you alternate the layers of the syrup and the
7 dusting mix, and then a finishing coating, which kind of gives it sort of a
8 shine, and then a shellacking or polishing stage. And Stahl teaches a multi-
9 level chewing gum manufacturing process, where in fact Cherukuri, as I
10 stated previously, is directed toward the one-step or one-syrup method which
11 is in fact just doing the one step where you alternate syrup and dusting
12 mixes. And Cherukuri explicitly states that after sufficient amount of
13 coating has been applied to the pieces of the comestible to be coated, the
14 coating pieces will be smooth and polished and otherwise finished without
15 the need for applying a second coating syrup or finishing syrup.

16 And similarly, the presently claimed invention is directed toward chewing
17 gum process -- or chewing gum products that are able to be manufactured
18 solely by alternating syrup and dusting levels as well. The process provides
19 the advantage that a large amount of coating can be applied in a realistic
20 amount of time, and when you add a shellacking agent to the final product, it
21 sort of keeps moisture in instead of allowing moisture to pass to and from
22 the product. So by not providing that shellacking step, you can provide a
23 product that's more shelf stable and that doesn't degrade as quickly, because
24 there's not as much moisture retained therein. So because Stahl teaches a

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1 typical chewing gum process, it teaches away from both Cherukuri and the
2 present claims.

3 I would also like to point out that in our experiments, experiments 1 through
4 6 in the specification, the advantages of the present chewing gum product
5 are explicitly stated. You'll see that the experiments show very clearly
6 through blood testing and all of these consumer testing that the absorption of
7 caffeine that's provided in the coating of a chewing gum is much quicker
8 than when caffeine is split between the coating, or I'm sorry, the center and
9 the coating. So having it just in the coating provides quicker absorption.

10 Now when you provide it when it's split between the center and the coating,
11 it absorbs about as quickly as it does when you ingest caffeine through
12 beverages such as coffee or colas, and when you ingest through coffees or
13 colas, that in fact is even quicker than when caffeine is absorbed by pills. So
14 at the end of the day, this invention provides a quicker absorption of caffeine
15 which results in better bioavailability through the oral mucosa of the
16 medicament.

17 You'll notice that the experiments all have coatings of 50 to 66 percent. So
18 when you look, for example, at a good example would be experiment
19 number 5 where you see the chewing gum versus beverages, and it
20 specifically shows that the chewing gum has a much faster delivery when
21 the caffeine is absorbed through the oral mucosa when compared to the same
22 level in beverages such as a cola or a coffee, as I stated. In that example, all
23 of the caffeine was located in the coating, not split between the center and
24 the coating. However, when you look at example 6 where the caffeine is
25 split between the center and the coating, it still shows that chewing gum has

1 a faster delivery than when you ingest, for example, like a No-Doz caffeine
2 pill or something like that.

3 So at the end of the day, having this overcoating of over 50 percent coating
4 in the chewing gum and having a medicament in that coating provides a
5 faster absorption of whatever that medicament is and provides better
6 availability or bioavailability of that medicament.

7 JUDGE MILLS: You don't have any examples in your specification
8 comparing your over-coated gum with prior art gums at all?

9 MS. LYNCH: No, not any prior art gums having only in the coating.

10 JUDGE MCCOLLUM: Which is -- then that's what --

11 MS. LYNCH: Oh, wait, I --

12 JUDGE MCCOLLUM: -- the WIPO reference teaches, it's in the
13 coating, right?

14 MS. LYNCH: Pardon me. Hang on for just one second.

15 JUDGE MILLS: Stahl.

16 MS. LYNCH: Yes, Stahl. That's what Stahl teaches, yes. Yes,
17 correct.

18 Are there any other questions that I can clarify for you while I'm
19 here?

20 JUDGE MILLS: I don't have any. Do either of you?

21 JUDGE GREEN: No, I don't have any.

22 JUDGE MILLS: I think we understand your position, so --

23 MS. LYNCH: Okay.

24 JUDGE MILLS: -- that will be it. Thank you very much.

25 MS. LYNCH: Okay.

1 JUDGE MILLS: If you wouldn't mind taking a quick minute if
2 there -- do you have any other questions for -- the court reporter might have
3 other questions for you, I don't know, about spellings.

4 MS. LYNCH: Okay.

5 (Whereupon, the hearing concluded on June 25, 2009.)
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